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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/667,655	09/23/2003	Nyle S. Elliott	A-8601	9116
<p>7590                    05/22/2007 HOFFMAN, WASSON &amp; GITLER, P.C. Suite 522 2361 Jefferson Davis Highway Arlington, VA 22202</p>			EXAMINER MARCETICH, ADAM M	
		ART UNIT 3761	PAPER NUMBER	
		MAIL DATE 05/22/2007	DELIVERY MODE PAPER	

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>
	10/667,655	ELLIOTT, NYLE S.
	<b>Examiner</b>	<b>Art Unit</b>
	Adam Marcetich	3761

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) Responsive to communication(s) filed on 02 March 2007.
- 2a) This action is **FINAL**.                    2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) Claim(s) 1-23 is/are pending in the application.
  - 4a) Of the above claim(s) 13-20 is/are withdrawn from consideration.
- 5) Claim(s) \_\_\_\_\_ is/are allowed.
- 6) Claim(s) 1-12,21 and 23 is/are rejected.
- 7) Claim(s) 22 is/are objected to.
- 8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on \_\_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.
 

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
  - a) All    b) Some \* c) None of:
    1. Certified copies of the priority documents have been received.
    2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
    3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)          | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)          | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____  | 6) <input type="checkbox"/> Other: _____                          |

## **DETAILED ACTION**

### ***Claim Objections***

1. Claim 1 is objected to because of the following informalities: the language "a first and second conductor extending from said aperture said alarm" is being read as "a first and second conductor extending from said aperture to said alarm." Appropriate correction is required.

### ***Claim Rejections - 35 USC § 112***

2. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.
3. Claim 23 recites the limitation "the circuit board" in line 3. There is insufficient antecedent basis for this limitation in the claim.

### ***Claim Rejections - 35 USC § 103***

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

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5. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

6. Claims 1-5, 7-11 and 21 are rejected under 35 U.S.C. 103(a) as being unpatentable over Brady (US Patent 6,723,040) in view of Nemir et al. (US Patent 6,843,766).

7. Regarding claim 1, Brady discloses an alert device for detecting and preventing bowel incontinence (abstract). Brady further discloses a pad member (column 5, lines 13-10 and Fig. 1, cuff 60), having an aperture (column 4, lines 10-12, Fig. 1, tubular body 18 passing through cuff 60). Brady further discloses an alarm (column 2, lines 53-55) first and second electrical conductors extending from an aperture (column 2, lines 50-53; column 4, lines 60-62 and Fig. 1, conductors 44 and 46), a plug (Fig. 1, element 18 and column 4, lines 10-12), third and fourth conductors on a plug (column 4, lines 58-62 and Fig. 2, sensors 40 and 42).

Brady lacks a plug removably secured to a pad. Nemir discloses a pad to prevent seepage past a probe (column 3, lines 56-60). Nemir solves the problem managing fecal incontinence with a means for blocking passage of stool (column 2, lines 58-67). The pad of Nemir is adaptable to fit around a probe, and therefore is adaptable to be

removably attached to the probe of Brady. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to combine the invention of Brady as discussed with the pad of Nemir in order to prevent seepage as called for by Nemir.

8. Regarding claim 2, Brady discloses an audible alarm (column 2, lines 53-55).
9. Regarding claim 3, Brady lacks an alarm emitting an audible alarm. Nemir discloses an alarm including a visible alarm (column 5, lines 26-36, especially line 32 and column 7, lines 8-10). Nemir provides a means of alerting patients who may be unable to hear an alarm. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to combine the invention of Brady as discussed in paragraph 7 above with the visible alarm of Nemir in order to alert patients unable to hear an alarm.
10. Regarding claim 4, Brady discloses a vibratory alarm (column 7, lines 25-29).
11. Regarding claim 5, Brady discloses transmitting an alarm signal to a remote location (column 7, lines 12-18).
12. Regarding claim 7, Brady discloses a flexible material composing the inflatable cuff (column 5, lines 19-21).
13. Regarding claim 8, Brady discloses an inflatable cuff encircling the plug as discussed in paragraph 7 above.
14. Regarding claim 9, Brady discloses third and fourth conductors in the form of rings, as discussed in paragraph 7 above. With respect to the claimed duplication of rings, the MPEP 2144.04(VI)(B) requires an invention made through duplication of parts

to have a "new" and "unexpected" result for patentability. The claimed invention lacks these qualities. It is well known in the art that providing additional electrical contacts provides redundancy to ensure connection if one electrode fails. Therefore, the duplication of rings does not provide a "new" and "unexpected" result.

15. Regarding claim 10, Brady lacks an absorbent sleeve. Nemir discloses a pad suitable to pass around the tube of Brady, as discussed in paragraph 7 above. The pad of Nemir substantially forms an absorbent sleeve. With respect to motivation, see paragraph 7 above.

16. Regarding claim 11, Brady discloses a charcoal filter (column 2, lines 63-64).

17. Regarding claim 21, Brady discloses third and fourth conductors in the form of rings, as discussed in paragraph 7 above. Dividing each conductor into an upper and lower ring substantially constitutes a duplication of parts. See paragraph 7 above for rationale and motivation. With respect to the upwardly extending section extending between the upper and lower rings, Brady discloses conductors 44 and 46, which are capable of extending between a pair of divided rings placed in electrical connection.

18. Claim 12 is rejected under 35 U.S.C. 103(a) as being unpatentable over Brady and Nemir in view of Nielsen et al. (US Patent 6,764,474). Brady and Nemir lack an adhesive ring. Nielsen discloses an adhesive wafer having a hole for the purpose of adhering an ostomy device to a patient (5, lines 19-21). Having a hole and being substantially round, the adhesive wafer of Nielsen is adaptable to be attached to one side of the pad of Nemir as discussed in paragraph 7 above. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to

combine the invention of Brady and Nemir as discussed with the adhesive ring of Nielsen in order to prevent movement of the pad with respect to the patient when in use.

19. Claim 6 is rejected under 35 U.S.C. 103(a) as being unpatentable over Brady and Nemir in view of McDonnell (US Patent 4,121,589). Brady and Nemir lack mating threads securing a plug to an aperture. McDonnell discloses threads for the purpose of securely engaging an ostomy appliance to a patient (column 4, lines 4-7 and Fig. 1, element 7). The plug of Brady is adaptable to interface with the threading of McDonnell. The pad of Nemir is adapted to fit around a plug as discussed in paragraph 7 above, and is therefore also adaptable to interface with the threading of McDonnell. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to combine the invention of Brady and Nemir as discussed in paragraph 7 above with the threading of McDonnell in order to provide secure engagement between the colostomy device and patient.

#### ***Response to Arguments***

20. Applicant's arguments filed 2 March 2007 have been fully considered but they are not persuasive. Applicant states that Brady (US Patent 6,723,040) lacks an aperture having conductors. Brady discloses a pad with a probe passing through it, necessitating an aperture in the pad. See paragraph 7 above.

***Allowable Subject Matter***

21. Claim 22 is objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

A search for incontinent alert devices having a tubular structure with a ring-shaped sensor revealed prior art, which has been made of record. However, no instance of prior art discloses a ring electrode present on an inner surface of a tubular structure.

***Conclusion***

22. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

23. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure:

- ❖ Fisher et al. (US Patent 4,813,422)
- ❖ Prager (US Patent 4,351,322)
- ❖ Millot et al. (US Patent 6,171,289)

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Adam Marcketich whose telephone number is 571-272-2590. The examiner can normally be reached on 8:00am to 4:30pm Monday through Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Tatyana Zalukaeva can be reached on 571-272-1115. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Adam Marcetich  
Examiner  
Art Unit 3761

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AMM 5/11/07

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SUPERVISORY PRIMARY EXAMINER

